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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,852	08/31/2001	Kevin P. Baker	P2548PIC13	8469

7590 08/12/2003

Brinks, Hofer, Gilson & Lione
NBC Tower Ste 3600
455 N. City Front Plaza Dr
Chicago, IL 60611-5599

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

12

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,852

Applicant(s)

BAKER ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/16/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 22-27 are pending in the present application. This Office action is in response to Paper No. 11, filed 26 May 2003. Applicant's amendment in Paper No. 11 does not fully comply with the current amended practice. Applicant has indicated Claim 22 as "withdrawn." Claims drawn to a non-elected invention are "withdrawn" as a result of a restriction requirement. See MPEP Sec. 801 and 37 CFR 1.142(b). No restriction has been issued over the pending claims. Therefore, it is unclear if Applicant intends to cancel claim 22. If so, a proper amendment indicating the cancellation of claim 22 is required.

Claim Objections

Claim 26 is objected to because of the following informalities: Claim 26 recites the article "a" before the word "labeled." This appears to be a typographical error not present in the preceding forms of Claim 26. Normally, such an inconsistency would render the amendment improper. However, as a courtesy to applicant it is objected to in the present action. Appropriate correction is required.

Response to Amendment

Claims 22-27 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 22 and 27 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Claims 22-27 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Applicant has argued that one of skill in the art would be able to make antibodies using methods known in the art and use the claimed antibodies to identify the protein, PRO361, disclosed in the specification. At issue, under the enablement requirement of 35 U.S.C. 112, first paragraph is whether, given the wands factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). After consideration of Applicant's disclosure, the function of PRO361 appears to be unknown. Applicant surmises that PRO361 is either a mucin or chitinase that may be associated with cancer, plant pathogenesis or receptor functions. See specification page 59, lines 1-4. Because the function of the protein is unknown one of skill in the art would have to engage in an inordinate amount of work and experimentation to find out not only the identity of what the antibodies of PRO361 are useful for but also the use of PRO361, itself.

What Applicant requires of one of skill in the art amounts to an "invitation to experiment" in order to make use of antibodies to a protein, PRO361, with unknown function or activity. Under the law, the disclosure "shall inform how to use, not how to find out how to use for themselves." See *In re Gardner* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). For these reasons and those discussed in the previous Office action, the present claims fail to meet the enablement requirement of 35 U.S.C. 112, second paragraph.

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Claims 22 and 27 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 27 have been rejected as being vague and indefinite because it is unclear what applicant intends for the meanings of the words "binds," as claim 22 and "specifically binds," as in claim 27. Applicant has made a general assertion that specific binding is known in the art, however, has provided no definition or explanation to overcome any confusion with the phrase "specifically binds" alone or overcome the confusion as to what the difference between the term in claim 22 and 27 is.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
August 4, 2003



JAMES KETTER
PRIMARY EXAMINER